IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Joseph R. BYRUM		Art Unit:	1637
Appln. No.:	09/421,106	Examiner:	Young J. Kim
Filed:	October 15, 1999	Atty. Docket:	16517.142
Title:	**Nucleic Acid Molecules and Other Molecules Associated with Plants**		

APPELLANT'S BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Mail Stop Appeal Brief - Patents

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on June 6, 2003. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Appellant is unaware of any Appeals or Interferences related to this Appeal.[1]

[1] Appellant is aware that the U.S. Patent and Trademark Office has provisionally rejected co-pending application no. 09/552,087 (filed April 21, 2000) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 16 of the present application. *See* Office Action mailed September 19, 2001 (Paper No. 7), and Office Action mailed October 8, 2002 (Paper No. 13), in application no. 09/552,087.

3. Status of Claims

Claims 1-9, 16 and 19-24 are pending. Claims 1-9, 16 and 19-24 stand finally rejected under 35 U.S.C. § 101 and under 35 U.S.C. §112, first paragraph, as allegedly lacking both enablement and written description. Appellant appeals all of the rejections of claims 1-9, 16 and 19-24.

4. Status of Amendments

Applicant has not filed any responses in this case subsequent to the Final Office Action mailed March 7, 2003 (Paper No. 25) ("Final Action").

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule, which nucleic acid molecule is capable of specifically hybridizing, under conditions of 6.0 x sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 x SSC at 50°C, to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 2, 3, 4, 5, 6, 7, 9, 10 and complements thereof. Specification at page 8, line 24 through page 14, line 25. The invention is further directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 8. *Id.* The present invention is further directed to a vector comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10. Specification at page 9, lines 3-5, and page 59, lines 7-20.

6. Issues

The issues in this Appeal are:

(a) whether claims 1-9, 16 and 19-24 are unpatentable under 35 U.S.C. § 101 as allegedly not being supported by a specific asserted utility or a well established utility;

(b) whether claims 1-9, 16 and 19-24 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claims 1-9, 16 and 19-24 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description.

7. Grouping of Claims

Patentability of claims claims 1-9, 16 and 19-24 is addressed together in Sections 9.A through 9.D below.

8. Preliminary Remarks

Applicant thanks the Examiner for withdrawing the rejection of claim 9 under 35 USC §112, second paragraph, and the rejection of claim 1 under 35 USC § 102(b). Applicant further thanks the Examiner for withdrawal of the objection to the specification for failure to comply with the Sequence Rules set forth in 37 CFR §§ 1.821 through 1.825.

9. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicant has met his part of the bargain – he has disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acids provide at least this benefit, they satisfy the utility requirement

of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicant has provided an adequate description of the claimed nucleic acids that demonstrates Applicant's possession of the claimed invention. Each genus of claimed nucleic acid molecules, *i.e.*, the nucleic acid molecules comprising the nucleic acid sequences of SEQ ID NOs: 1 through 10 and their complements, has been described by the recitation of a common structural feature – the nucleotide sequences of SEQ ID NOs: 1 through 10, and their complements, respectively – which distinguishes molecules in the genus from molecules not in the claimed genus. Because the specification demonstrates that Applicant has possession of (and has provided an adequate description of) the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. The Claimed Nucleic Acids Have Legal Utility

Pending claims 1-9, 16 and 19-24 were erroneously rejected under 35 U.S.C. § 101 because the claimed inventions were allegedly not supported by either a "specific and/or substantial utility or a well established utility." Final Action at pages 2-7. According to the Final Action, "[t]he question is whether the claimed nucleic acids can be useful as probes, not by their inherent property of being able to hybridize to their complement, for all nucleic acids can specifically hybridize to their complements, but whether or not the result of the hybridization gives a 'real world' or immediately apparent utility to a skilled practitioner in the art. The answer to that question, based on the Applicants' disclosure is 'no.' " Final Action at page 3.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v.*

Manson. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicant has asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example use to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling. *See, e.g.*, specification at page 47 line 17 through page 54, line 16, and page 54, lines 17-26. Either of these utilities alone is enough to satisfy Section 101. Because Applicant need only establish a single utility to satisfy 35 U.S.C. § 101, and he has done so in the present case,

the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

Applicant has asserted that the claimed nucleic acid molecules[2] are themselves useful for utilities disclosed in the specification, *e.g.*, to detect the presence or absence of polymorphisms, and as hybridization probes for expression profiling. The specification also discloses additional utilities for the claimed nucleic acid molecules, including introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to screen for compounds such as a herbicide. Specification at page 77, line 8 through page 78, line 11. For example, a compound can be provided to both an antisense plant and a control plant (no antisense) and the effect of the compound on the plant can be monitored. Such a screen is analogous to a cell-based assay, which has a legally sufficient utility.[3] Thus, the use in such a screen of a plant or plant cell having an introduced claimed nucleic acid molecule is a legally sufficient utility. Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of mRNA in a sample, and use as molecular markers.[4]

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[2] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicant is not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[3] *See, e.g.*, MPEP § 2107 at page 2100-32.

[4] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

As admitted by the Examiner, Applicant's disclosure would allow one of skill in the art to conclude "that the nucleic acid [of SEQ ID NOs: 1 through 10] was present in a sample." Final Action at page 4. The Examiner further asserts that determining that a nucleic acid was present in a sample "does not provide any immediately apparent utility resulting from the detection of the nucleic acid." Final Action at page 4. This latter assertion is incorrect in light of the state of the art. For example, it is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that an RNA corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect and compare expression changes in tissue samples taken from organisms grown under different conditions, *e.g.*, drought stress, cold stress, exposure to pathogens, or exposure to chemical compounds. Furthermore, as microarrays allow rapid, simultaneous expression analysis of thousands of sequences, informative *patterns* of expression are derived from the microarray expression data. Contrary to the Examiner's assertions, the skilled artisan need not conduct " 'further research' in order to be able to conclude its immediately apparent utility." *See* Final Action at page 4. Expression analysis is a **use** of the claimed nucleic acid molecules in a real world context.

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 47, line 17 through page 54, line 16. The Examiner argues that this utility, like all of the asserted utilities, is not specific or substantial, *see* Final Action at page 5, but does not provide *any legal support* for the proposition that detection of polymorphisms is not a legal utility. The Examiner's heavy, if not sole, reliance upon the Interim Utility

Guidelines has led to an interpretation of utility that contravenes well-established doctrines of utility developed in the courts.

Applicant reiterates that many of the disclosed utilities in this case, including detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates this utility by asserting that these uses are not "useful" because a scientist would not know how to use the information gathered. *See, e.g.*, Final Action at pages 4-5. However, the fact that, for example, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[5] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

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[5] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit – to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal utilities because the "specification does not describe the corresponding promoter, or any other specific nucleic acid molecule [identified by using the claimed nucleic acid sequence as a probe or primer], sufficient to inform one skilled in the art that it has been isolated, [and so] there can be no "immediate benefit to the public" in using the claimed nucleic acid molecule in this capacity." Final Action at page 7. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used, via hybridization, in real world applications such as to isolate nucleic acid molecules of other plants and organisms such as alfalfa, barley, *Brassica*, broccoli, cabbage, etc.[6] Specification at page 33, lines 8-24. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and so has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

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[6] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicant to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

As apparently acknowledged by the Examiner, *see, e.g.*, Final Action at page 5, lines 16 through 20, there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, Applicants reiterate that it is factually incorrect that this use is not "specific" to the claimed nucleic acids. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter that is active in *Glycine max*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

It appears that the Final Action is arguing that the disclosed uses are legally insufficient or "insubstantial" under 35 U.S.C. § 101, but such an argument has no basis in law. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[7]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example, to perform high-throughput microarray analysis of expression changes in a series of tissue samples. The detection of expression changes provides an immediate benefit to the public because, for example, it enables a plant geneticist to rapidly identify relationships or patterns within the expression changes corresponding to various tissues of organisms grown under various different conditions. This comparative information about a plant's expression profile under different growth conditions, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the analysis of gene expression, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has

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[7] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *See, e.g., In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Compare Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 706.03(a)(1). Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[8] A challenge to the credibility of a utility is essentially a challenge

[8] Examples of incredible utilities are given in MPEP § 2107 at page 2100-26, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels

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directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a)(1).

Applicant has explicitly identified specific and substantial utilities, not only in the specification, but in Applicant's Response dated December 12, 2000 at page 5, lines 13 through 24. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no conclusive evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1-9, 16, and 19-24 have been erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at pages 7-8. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any

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upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides An Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that SEQ ID NOs: 1-10 are adequately described by the specification, the adequacy of the written description of the claimed invention has been challenged by the Examiner because the nucleic acid molecules of all of the claims are allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 8. The Examiner contends that Applicant was "not in possession of genomic that contain the common EST fragment, which are embraced by the open-ended language of the claims." Final Action at page 9. This is not a proper basis for a written description rejection of a "comprising" claim. If it was, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicant was in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicant's Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicant had possession of SEQ ID NOs: 1-10 and their complements, and vectors comprising the claimed nucleic acid molecules and therefore, the claimed invention.

Applicant has provided the nucleotide sequences required by the claims, *e.g.*, SEQ ID NOs: 1-10, vectors comprising these nucleotide sequences, and bacterial artificial chromosomes comprising these nucleotide sequences, and has thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences, or that hybridize under specific conditions to the recited sequences does not mean that Applicant was any less in possession of the claimed nucleic acid molecules.[9] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80

[9] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence required by the claims (SEQ ID NOs: 1 through 10), for example, it describes vectors comprising the claimed nucleic acid molecules (specification at page 59, line 7 through page 67, line 5). Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequences (SEQ ID NOs: 1 through 10) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[10] in particular at page 13, lines 15-19 (describing sequences with labels to facilitate detection), page 34, line 9-17 (describing fusion nucleic acid molecules), and page 79, lines 12-20 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

(2) Applicant Has Described the Claimed Invention

The Examiner asserts that because Applicant has not disclosed "genomic materials that contain the common EST fragment," Applicant has allegedly not adequately disclosed the claimed genera of nucleic acid molecules. Final Action at page 9. The Examiner appears to assert that each nucleic acid molecule within the claimed genera must be described by its complete structure. Final Action at page 9. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43

[10] It is established patent jurisprudence that Applicant need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicant has satisfied that test for written description.

In particular, Applicant has disclosed common structural features, for example the nucleotide sequences of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, etc. For example, if a particular vector contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of vectors comprising a nucleic acid sequence of SEQ ID NO: 1.[11] *See* claim 8. Moreover, closely related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable - they either contain the nucleic acid sequences of SEQ ID NOs: 1-10 (or complements thereof), or hybridize under the claimed conditions to SEQ ID NOs: 1-10 (or complements thereof), or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, claims 1-9, 16 and 19-24 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

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[11] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a vector contains a nucleic acid sequence of SEQ ID NO: 5, then it is a member of the claimed genus of vectors comprising a nucleic acid sequence of SEQ ID NO: 5. *See* claim 8.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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I. APPENDIX A

1. A substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing, under conditions of 6.0 x sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 x SSC at 50°C, to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 2, 3, 4, 5, 6, 7, 9, 10 and complements thereof.

2. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a microsatellite sequence.

3. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a region having a single nucleotide polymorphism.

4. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 2, 3, 4, 5, 6, 7, 9, 10 and complements thereof.

5. The substantially purified nucleic acid molecule according to claim 4, wherein said nucleic acid molecule further comprises a bacterial ORI site.

6. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule has a promoter or partial promoter region.

7. The substantially purified nucleic acid molecule according to claim 6, wherein said promoter region comprises a CAAT cis element and a TATA cis element and an additional cis element.

8. A vector comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10.

9. The vector according to claim 8, wherein said nucleic acid sequence is a first nucleic acid sequence, and wherein said vector further comprises a second nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10, wherein said second nucleic acid sequence is not identical to said first nucleic acid sequence.

16. The vector of 8, wherein said vector is a bacterial artificial chromosome.

19. A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 8.

20. The substantially purified nucleic acid molecule according to claim 19, wherein said nucleic acid molecule comprises a microsatellite sequence.

21. The substantially purified nucleic acid molecule according to claim 19, wherein said nucleic acid molecule comprises a region having a single nucleotide polymorphism.

22. The substantially purified nucleic acid molecule according to claim 19, wherein said nucleic acid molecule further comprises a bacterial ORI site.

23. The substantially purified nucleic acid molecule according to claim 19, wherein said nucleic acid molecule has a promoter or partial promoter region.

24. The substantially purified nucleic acid molecule according to claim 23, wherein said promoter region comprises a CAAT cis element and a TATA cis element and an additional cis element.